

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 3, 2019

Leesha N. Square Regulatory Specialist Arch Chemicals Inc. 1200 Bluegrass Lakes Parkway Alpharetta, GA 30004

Subject: PRIA Label Amendment – Removing the Closed System Requirement for Metal

Working Fluids

Product Name: Densil DG 45 Fungicide EPA Registration Number: 1258-1286

Application Date: 07/09/2018 Decision Number: 542741

Dear Ms. Square:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(A), subject to the following conditions:

- 1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
- 2. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. N-Butyl-1, 2-benzisothiazolin-3-one GDCI- GDCI-012401-1087

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,

Zeno Bain, Product Manager 33 Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Stamped Label

DENSIL® DG 45 Fungicide

For the Preservation of Metalworking Fluids, ¹Coatings, and ¹Other Construction Materials

45%
<u>55%</u>
100%

¹Coatings and Other Construction Materials not approved for use in California

ACCEPTED

May 03, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 1258-1286

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF INHALED: MOVE PERSON TO FRESH AIR. IF PERSON IS NOT BREATHING, CALL 911 OR AN AMBULANCE, THEN GIVE ARTIFICIAL RESPIRATION, PREFERABLY MOUTH-TO-MOUTH, IF POSSIBLE. CALL A POISON CONTROL CENTER OR DOCTOR FOR FURTHER TREATMENT ADVICE.

IF ON SKIN OR CLOTHING: TAKE OFF CONTAMINATED CLOTHING. RINSE SKIN IMMEDIATELY WITH PLENTY OF WATER FOR 15-20 MINUTES. CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT.

IF IN EYES: HOLD EYE OPEN AND RINSE SLOWLY AND GENTLY WITH WATER FOR 15-20 MINUTES. REMOVE CONTACT LENSES, IF PRESENT, AFTER THE FIRST 5 MINUTES, THEN CONTINUING RINSING EYE. CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

IF SWALLOWED: CALL A POISON CONTROL CENTER OR DOCTOR IMMEDIATELY FOR TREATMENT ADVICE. HAVE PERSON SIP A GLASS OF WATER IF ABLE TO SWALLOW. DO NOT INDUCE VOMITING UNLESS TOLD TO BY A POISON CONTROL CENTER OR DOCTOR.

MEDICAL EMERGENCY INFORMATION CENTER 1-800-654-6911

HAVE THE PRODUCT CONTAINER OR LABEL WITH YOU WHEN CALLING A POISON CONTROL CENTER OR DOCTOR OR GOING FOR TREATMENT.

NOTE TO PHYSICIAN: POSSIBLE MUCOSAL DAMAGE MAY CONTRAINDICATE THE USE OF GASTRIC LAVAGE FOLLOWING INGESTION.

See Additional	Precautionary Statements	on Side Panel
Contents:	Lbs. Net Minimum	US Gallons

EPA Reg. No. 1258-1286 Lot Number: Product Code: EPA Est. No. 83801-GBR-001

Manufactured for: Arch Chemicals, Inc. 1200 Bluegrass Lakes Parkway Alpharetta, GA 30058 For information on spills, call 1-800-654-6911

DENSIL® is a registered trademark of Arch UK Biocides Ltd.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER.

Corrosive. Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, chemical-resistant gloves, coveralls, or long-sleeved shirt and long pants, and shoes plus socks when handling this product. Harmful if swallowed or absorbed through skin. May be fatal if inhaled. Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination R or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air-purifying respirator with OV cartridges and combination. Do not breathe vapors or spray mist. Wash thoroughly after handling and before eating, drinking or using tobacco. Remove and wash contaminated clothing before reuse. May cause allergic skin reaction.

PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear: coveralls or long-sleeved shirt and long pants, chemical resistant footwear and socks, goggles or face shield and chemicals-resistant gloves (usually > 14 mils; Barrier Laminate or Viton)

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state water board or regional office of the EPA. Do not contaminate water by cleaning of equipment or disposal of wastes.

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

PESTICIDE STORAGE:

Protect from frost. DO NOT FREEZE. If frozen, thaw and stir well before use.

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER DISPOSAL:

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container promptly after emptying. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

{For containers greater than 5 gallons} Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

(For containers less than or equal to 5 gallons) Triple rinse as follows: Empty remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

METALWORKING FLUIDS

Fluid Concentrate

Add this product to metalworking fluid concentrates at a level that ensures the final use dilution fluid will contain 55 to 445 parts per million (ppm) of product (25 to 200 ppm active ingredient).

Use Dilution Fluid

Note that grossly contaminated systems may require mechanical removal of fungal masses, and cleaning of the system before biocide treatment is begun.

Initial Dose: For noticeably fouled systems, add 0.47 to 3.94 lbs. (7 to 55.6 fl. oz.) of this product per 1000 gallons of fluid. This will generate a concentration of 25 to 200 ppm active agent.

Subsequent Dose: For maintenance of a clean system, add 0.09 to 0.58 lbs. (1.3 to 8.6 fl.oz.) of this product per 1000 gallons of fluid on a periodic basis to maintain microbial control. This quantity will generate a fungicide concentration of 5 to 30 ppm active ingredient. The frequency of maintenance dosing will be affected by the amount of fluid lost to drag out and other displacements, but also by the severity of the contamination, by the system design, by the effectiveness of system filtration, and by other system variables.

¹CONSTRUCTION MATERIALS

Many building construction materials support the growth of a wide range of bacteria, fungi and algae. The uncontrolled growth of these microorganisms either in the wet or dry stage can lead to aesthetic problems such as odor or surface staining or it can lead to premature product failure.

This product has been found to be an effective wet state preservative at concentrations of 0.02% to 0.11%, and an effective dry state preservative at concentrations of 0.16% to 0.24%, based on the total weight of the substrate. Example end use applications are shown below:

For preservation of emulsions, dispersions, slurries, and thickeners including latex emulsions, urethane dispersions, mineral or pigment slurries (such as clay, kaolin, calcium carbonate, and titanium dioxide). For preservation of pulp and paper slurries and for preservation of paper coating compositions, including starch preparations. Add 0.02 – 0.11% of this product. Not for use in food contact paper products or paper coatings.

For preservation of adhesives, tape joint compounds, spackle, stucco, grout, glazing compounds, fillers, sealants, caulks, and weather stripping. Add 0.16 - 0.24% of this product. Not for use in food contact adhesives.

For preservation of manufactured paper and paperboard products such as insulation facing, wallboard facing, stationeries, and paper packaging. Add 0.16 – 0.24% of this product. Not for use in food contact paper products.

For preservation of composites, gypsum, perlite, plaster-like or mineral and cellulose materials. For preservation of ceiling tiles, partitions, dry wall and wallboard. Add 0.16 - 0.24% of this product.

For preservation of coatings. Add 0.16 - 0.24% of this product. Not for marine use.

¹Coatings and Other Construction Materials not approved for use in California.

PLASTICS:

Many plastics are considered to be resistant to microbial attack, but there are significant exceptions that merit preventative action by the use of antimicrobial additive. Plasticized PVC, polyurethane and silicones are particularly susceptible. The biodeterioration of products based on these types of plastics can be a serious problem for manufacturers. Failure to add the proper amount of antimicrobial additive can lead to premature product failure due to loss of mechanical strength, flexibility or adhesive strength. Also, adverse aesthetic problems such as musty odor, permanent staining or microbial surface growth can lead to customer complaints.

Densil® DG 45 Fungicide is effective against the microbes which degrade plastics (and plastic additives) or natural rubber and can increase the useful life of articles made from these materials. Densil® DG 45 Fungicide is effective in most plastic compositions and can be used to preserve natural rubber and such plastics as PVC, polyurethane, silicone, acrylics, and others to produce articles such as; coated fabric (e.g. ski wear, raincoats, tents, seat covers), floor coverings, underlay and mats, vinyl wall coverings, tarpaulins and awnings, roofing membranes, synthetic leather (e.g. sneakers and training shoe uppers), swimming pool liners, ornamental pond liners, appliance gaskets (e.g. washers, refrigerator), shoe soles, mid-soles and outers, sealants, sealers, coatings, caulks, weather stripping and non-food contact adhesives, pet toys and general household items (shower curtains, bath mats, sink drain mats, rubber or plastic coated wire shelving and dish drainers), auto parts (e.g. landau tops, door seals, shock absorbers), foam (e.g. seat cushions, gaskets, insulation), tubing (e.g. marine hose and sleeving), electrical and pipe wrap, furniture (e.g. outdoor, leisure, water bed liners, cushions, covered foam mattress padding, covered foam pillow cushions). Do not use this product to treat food/feed or drinking water contact items or toys. Densil® DG 45 Fungicide has been found to be an effective polymer preservative at concentrations of 0.03% to 1.0% based on the total weight of the substrate. Typical range of concentrations on which trials can be based are:

APPLICATION % Densil® DG 45 Fungicide (based on total weight of final product)

Plasticized PVC	0.066 to 1.10%
Polyurethane	0.11 to 1.10%
Silicones	0.11 to 2.2%
Polyesters	0.11 to 2.2%
Polyolefins	0.11 to 2.2%
Acrylics	0.11 to 2.2%
Synthetic elastomers: such as	0.066 to 2.2%

butadiene-styrene, styrene-Isoprene and acrylonitrile-

Butadiene-styrene

Natural latex rubber 0.066 to 1.1%

Do not go above the application rates. The concentration required to give protection depends on several factors. These include the susceptibility of the system to microbiological degradation, the extent to which micro-organisms can gain access, the species involved, pH, temperature, moisture and length of time for which protection is required.

INCORPORATION OF DENSIL® DG 45 FUNGICIDE INTO POLYMERS

Do not use for any application involving direct or indirect food contact.

PVC plastisols: For addition to PVC plastisols Densil® DG 45 Fungicide liquid may be added along with the other additives. Do not go above the application rates. Calculate use levels based upon the total weight of the formulation.

Cross Linked Polyurethane: For addition to cross linked polyurethane and Densil® DG 45 Fungicide liquid to the polyol at a concentration that will yield the appropriate listed use level in the final product after reaction with the isocyanate component. Vanquish® 100 Antimicrobial may also be incorporated at an injection port of a reaction injection molding (RIM) machine.

Melt Processed Polymers: For addition to melt processed polymers (PVC, thermoplastic polyurethane, synthetic elastomers and thermoplastic acrylics etc.) Densil® DG 45 Fungicide liquid may be metered into the melt to yield the desired end use concentration. For example at the injection point in an extrusion system. Alternatively, Densil® DG 45 Fungicide liquid may be made into a concentrated chip (as above at up to 40% Densil® DG 45 Fungicide) and these chips blended with non preserved chips in the users plant to yield the desired end use concentration upon subsequent melt processing. For thermoplastic polyurethane, concentrated granules may also be produced by absorbing Densil® DG 45 Fungicide liquid to granules through shear mixing (up to 40% Densil® DG 45 Fungicide). These can be blended with non preserved polymer chips in the users plant to the desired use concentration and then further heat processed (i.e. via extrusion).

[Note to reviewer: Only one of the following 2 paragraphs will be used.]

[1.] PVC: This product may be added to the mixed liquid components or added to concentrate(s) that will be added to a blend of PVC resin and solids, shear mixed until a dry blend is achieved and then processed through extrusion, calendering, molding or other system. The concentrate must be used in proportion to untreated plastic and other inputs in the fabrication of plastic articles entering commerce so that the final concentration of active ingredient does not exceed the application rate range (0.03-0.5%) specified for the various plasticized PVC articles to be preserved.

[2.] PVC: This product may be added to the mixed liquid components or added to concentrate(s) that will be further processed to manufacture PVC articles or added to a blend of PVC resin and solids, shear mixed until a dry blend is achieved and then processed through extrusion, calendering, molding of other system. The concentrate must be used in proportion to untreated plastic and other inputs in the fabrication of plastic articles entering commerce so that the final concentration of active ingredient does not exceed the application rate range (0.03-0.5%) specified for the various plasticized PVC articles to be preserved.

Acrylics: In addition to the above, Densil® DG 45 Fungicide liquid can be added to the liquid monomers before polymerization, at levels to yield the desired use level in the final product after polymerization.

Silicone: For silicone sealants, the Densil® DG 45 Fungicide liquid may be added to the silicone oil before processing, or to the manufacturing vessel before packing off.

Natural Rubber: Densil® DG 45 Fungicide can be added to the latex.

The Arch Technical Service Group can provide additional guidance on the proper use of Densil® DG 45 Fungicide.